



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
ROSE, S	
ART UNIT	PAPER NUMBER
335	7

DATE MAILED: 07/26/89

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on April 14, 89 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-53 are pending in the application.
Of the above, claims 11-28, 30-45 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-10, 29, 46-53 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Claims 1-10, 46-53 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 are vague and indefinite because it is unclear how the chemical and physical properties of the polymer and the solvent must be related to enable the invention to operate. The claim is unduly broad because all biocompatible solvents will not dissipate from the implant. Therefore the claim lacks sufficient recitation of the chemical and physical properties to enable the functional step C. Additionally, the claim is unduly broad so that it is vague and indefinite because some non-reactive polymers exist which will not form solid implants in the body. An example is uncrosslinked polyvinylpyrrolidone. Claim 2 contains water soluble polymers. These will not form solid implants. Claims 2-10 are vague and indefinite because the Markush group is improperly expressed. The proper expression is "consisting of." Use of the expression "consisting essentially of" results in undue breadth. Claim 7 is vague and indefinite because it is unclear what the term "and/or" implies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed

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publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,7,8,46, and 52 are rejected under 35 U.S.C.

§ 102(b) as being clearly anticipated by Gurney '527.

Claims 1,2,6,7,46 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Widra '629.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3-5, 9, 10, 46-53 are rejected under 35 U.S.C. § 103 as being unpatentable over Widra '629 in view of Yolles '699.

Widra discloses the instant invention except for the specific polymers of claim 3, the specific solvents of claims 4, 9, and 10, and the specific drugs. Yolles exemplifies that polylactides are commonly used as biodegradable drug delivery devices. In addition, Yolles discloses a wide variety of drugs

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which can be employed in the invention. It would be obvious to one of ordinary skill in the art to use the biodegradable polymers of Yolles in the Widra device because Widra discloses the desirable characteristics if the device in terms of mallability, drug release and bioerodibility. Similiarly, it is an obvious design choice to incorporate any drug into the Widra device to correspond with the desired therapeutic effect. Therefore the invention as claimed is obvious.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication should be directed to Sharon Rose at telephone number (703) 557-3125.



Sharon Rose



C. FRED ROSENBAUM

S. P. E.

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